F. No. 2-17/2007 -CGHS/AMSD/Pt. 386-37
CGHS, Ayurvedic Medical Store depol,
Barracks No. 8 & 10, Bikaner House,
Shahjahan Road, New Delhi-11

Date: - 23-02-2010.

CIRCULAR

Sub: - Guidelines for Procurement of Ayurvedic Drugs in Central Government Health Scheme (CGHS).

The undersigned is directed to enclose herewith the Guidelines for procurement of Ayurvedic Drugs under Central Government Health Scheme (CGHS). These Guidelines will be effective from the year 2010-2011 onwards until further orders received from the ministry.

These issues with the approval by Secretary (Health & F.W) with the concurrence of IFD vide Dy.No.5370 dated 11/1/2010.

Dr. Anand.T.Gudivada,
C.M.O. (NFSG) l/c, AMSD.CGHS.HQ.

Copy to:

1. Additional Director, M.S.D. CGHS.
2. Additional Director, CGHS, H.Q.
4. Adviser (Ayurveda) Dept. of AYUSH. Red Cross buildings, N.D
5. Director, N.I.C. Nirman Bhavan with request to upload the copy of Guidelines on mohfw’s website.
6. T.S. Bhatia, D.S. Department of AYUSH with request to upload the copy of Guidelines on Department’s website.

Copy for information to:

1. Sr. PPS to Sec. (H &FW) MOHFW, Nirman Bhavan.
2. Sr. PPS to Sec. Department of AYUSH, IRCS Buildings.
3. Sr. PPS to DGHS. (H &FW) MOHFW, Nirman Bhavan.
4. PPS to A.S.&F.A. MOHFW, Nirman Bhavan
5. PPS to J.S. (V.C.) MOHFW, Nirman Bhavan.

Dr. Anand.T.Gudivada,
C.M.O. (NFSG) l/c, AMSD.CGHS.HQ
GUIDELINES FOR PROCUREMENT OF AYURVEDIC DRUGS IN CENTRAL GOVERNMENT HEALTH SCHEME (CGHS).

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GUIDELINES FOR PROCUREMENT OF AYURVEDIC DRUGS IN CENTRAL GOVERNMENT HEALTH SCHEME (CGHS).

1. Mode of Procurement:

The following modes of procedure can be used for procurement of Ayurvedic Medicines:

A. Procurement without inviting tenders / rate enquiry.
B. Procurement by inviting Tenders / rate enquiry.
C. Procurement through Local Purchase system.

2. Procurement without inviting Tenders / Rate enquiry:

Drugs and medicines which are manufactured by IMPCL (A Government of India Undertaking set up with specific objective of providing authentic Ayurveda and Unani Medicines to CGHS) may be procured without inviting tender / Rate enquiry at rates finalized by the Cost and Account Branch of the Department of Expenditure/ Ministry of Finance. Subject to IMPCL should provide barcode system for their list of manufacturing medicines from the next financial year.

3. Procurement by inviting Tenders / Rate enquiry.

Generic Medicines which are not in the list of medicines being produced by the IMPCL or the medicines which have been certified by the IMPCL having not produced for the period and Proprietary medicines as per the approved CGHS Formulary, under disease category may be procured from open market through tendering process by following Two-Bid procedure i.e. after techno-commercial analysis, the price bids of only techno-commercial acceptable bidders will be opened.

4. Eligibility of Firms.

a) Manufacturing units with an Average Annual turnover of Rupees 50 lakhs per year for the last 3 years.
b) The firms should not be black listed / debarred / banned by any State Governments / U.T./Central Government/Corporations/Local government Bodies for the preceding 3 years.
c) Firms should be able to provide EMD of Rupees 25,000/- and
performance security of Rupees 50,000/- EMD for a period of 4.5 months and performance security for a period of 3 years.

d) Photo copy of forms of preceding three financial years submitted regarding Sales Tax / VAT return STO, CST, Other State Taxes, Central Excise duty paid certificate. Etc. as applicable.

e) Statement of P & L Accounts and Balance Sheet of preceding three financial years of the firm / Company duly audited by a C.A. (Chartered Accountant).

f) Recently issued Physical existence certificate of the manufacturing unit from the concerned Drug Licensing Authority. If the units are more than one in such condition all the units’ existence certificate.

g) Firm / Company should posses for the last three years Good Manufacturing Practice (GMP) certificate issued under schedule “T” Of Drugs & Cosmetics Act 1940 Rules there under in force.

h) Drug Manufacturing License should be valid at the time of tender, and should continue throughout the period of tender year. If the license is happening to expire, Proof of renewal from the Licensing authority with under taking is mandatory.

i) The owner / owners of the Firm / Company ever been convicted for Contravening the provision of Drugs & Cosmetics Act & Rules there Under in the past? If so, furnish details. Furnish a certificate from Licensing Authority (ISM / AYUSH) that now the firm / Company have been exonerated. Or an affidavit to be submitted by the firm.

j) The manufacturing license of the Firm / Company suspended or Cancelled in the past? If so, furnish particulars and attach documentary proof.

k) Non- conviction certificate for last three years issued by the DRUGS CONTROLLER OF THE STATE / LICENSING AUTHORITY or an affidavit to be submitted by the firm and Certificate to the effect the list of items approved and intended to quote.

l) Firms should be capable to provide barcode system for the selected medicines on the label and packing unit.

5. **Validity of Rate Contract**

Normal validity of Rate Contract (R.C.) will be for a period of two years, which may be extended, for a period of six month in one instance, i.e. upto a period of one more year on the discretion of the Ministry and at the existing terms and conditions.

[Signature]

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Barak No.8 & 10,
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6. Preparation of Formulary:

Both the following type of formularies will be approved through the Director, CGHS by competent authority in the Department of Health MOHFW on the recommendations of the Formulary Committee (for OPD medicines) and the Medical Superintendent of Ayurveda Hospital, Lodhi Road (for IPD medicines). Any modifications/ addition/ deletion to these Formularies may be made by Department of Health, in Technical consultation with Advisor (Ayurveda), in respect of OPD medicines and MS Ayurveda Hospital, Lodhi Road, in respect of IPD Medicines.

6.1 Formularies for OPD medicines:

The following formularies of Ayurvedic Medicines shall be prepared for procurement by the AMSD CGHS. The formulary may be revised every two years: On the basis of recommendations of medicines by the treating Ayurvedic doctors under CGHS all over India / Delhi.

(a) Medicines manufactured by IMPCL – Generic medicine (Shastrokt Aushdhi), Patent / Proprietary medicine / (Branded medicines)

(b) Formulary for procurement of Medicines not manufactured by IMPCL from private manufacturers consisting of:

(i) Rates and Generic Medicines not in the list of IMPCL or certified by the IMPCL as not manufactured by them for time being. (Shastrokt Aushdhi).

(ii) Disease categories (Rogadhikar) under which patent or proprietary Medicines are being procured. (Branded Medicines)

6.2 Formulary for IPD (Ayurvedic Hospital).

This formulary will be prepared by the Medical superintendent of the Ayurvedic Hospital, Lodhi Road, on the basis of requirements of the treatment available in IPD of the hospital.

[Signature]
7. **Floating of Tender / Rate enquiry.**

The tender / rate enquiry shall only be floated in respect of those formulary Generic Medicines or disease category medicines which are not being manufactured by the IMPCL. The tender/ rate enquiry, based on procurement policy, shall be floated by the in-charge Ayurvedic Medical Store Depot, after getting the same approved from the Ministry, through Director, CGHS.

8. **Tender opening committee:**

Tender will be opened on the scheduled date and time by the tender Opening committee in the presence of the representatives of the firms, as per the provisions of the General Financial Rules. The constitution of the Tender Opening Committee is given at Annexure-A.

A) **Tender Scrutiny / tabulating committee:**

All the tender documents and sample boxes of the medicines submitted by the bidders will be scrutinized by in-charge, Ayurvedic Medical Store Depot, assisted by two Senior Ayurvedic Doctors of the CGHS, to be nominated by the Director, CGHS, which will segregate applicant tenderers into eligible and non-eligible categories.

B) **Medicine Selection Committee:**

In second phase on the basis of comparative statement of the medicines of a given group will be prepared and placed before the medicine selection Committee by the in-charge, Ayurvedic Medical Store depot for selection of that group medicine on the basis of selection criteria. Constitution of the committee is given at Annexure -A

9. **MEDICINE SELECTION CRETERIEA:**

The following will act as guiding characteristics/ features of medicines for the purpose of selection of medicines by the Medicine Selection Committee:
a. Lab report, from Govt. approved labs (Under drug Act approved by AYUSH/DCC (1) / State DTL Etc.) / NABL accredited labs, firm’s protocol and other objective parameters.

b. Scientific support in the form of clinical trials and number of publications on the product in various journals. (For the medicine manufactured by the concerned firm)

c. Production capacity of the product along with batch capacity and number of batches manufactured during the last three years.

d. Evaluations of the samples as per classical book reference. (Examination for Organoleptic characters of the medicine as per A.F.I / referred classical book)

10. Finalization of Rate contract.

a. The in-charge Ayurvedic Medical Store Depot will prepare a comprehensive list of medicines selected by the committee along with the rates quoted by the firms.

b. Final approval for the Rate Contract will be given by the Ministry, in accordance with the provisions of the General Financial Rules.

c. The approved Rate Contract will be intimated to the concerned firms.

d. Approved Rate Contract list will be circulated to all the CGHS Additional/Joint Director in-charge of CGHS cities outside Delhi.

e. The firms which are selected on Rate Contract will supply one set of each medicine from the same batch which has already been approved by CGHS, New Delhi, free of cost to all the CGHS Additional Directors outside Delhi directly as control sample. 4 sets of samples will be provided to AMSD as control sample.

11. Provisioning and Procurement

a. The Procurement of Ayurvedic Medicines for CGHS, Delhi will be made as per annual provisioning worked out on the pattern of DPAR (Daily Patients Attendance Rate) formula and annual demands submitted by I /c of the dispensaries / Units / Hospital. The provisioning of classical and patent / proprietary medicine of IMPCL and other firms will be made on the basis of the consumption of the last three years.

b. The first preference in CGHS procurement should go to IMPCL. CGHS will place purchase orders to IMPCL and the private firms on the basis of
expenditure with condition of minimum 3 supply orders in a financial year.

c. CGHS may procure medicines which are not supplied by the IMPCL from State Govts / Co-Operative Pharmacies provided they are willing to supply medicines on CGHS rate contract.

d. The ratio of 60:40 in terms of value in classical and proprietary medicines will be maintained in CGHS procurement.

f. The provisioning of the medicines will be recommended by a Provisioning Committee and will be approved by Ministry. The constitution of the Provisioning Committee is indicated as Annexure -A

12. Receipt of Supply and its Approval:

All supplies of medicines will be required to be made accompanied with analytic report from an approved laboratory/ NABL accredited laboratory in respect of each batch of medicine. The medicines received against supply orders shall be physically inspected by the official working in the receipt section with particular respect to condition of the container, container cartons, breakage quantity, labels, batch number, date of manufacturing, expiry date and book reference. Bulk supply of medicines will be open for inspection, at any time, by a senior Ayurveda Physician to be nominated by the Director, CGHS for these features and quality of medicines.

For medicines received from IMPCL as per the existing procedures, In-charge of the Ayurveda Stores Depot will be authorized for examination and certification of supplies.

13. Procedure for Approval / Rejection of the Bulk supply:

A. Panel of medical inspection committee comprising of 3 members each for two years with 2 months tenure will be prepared and approval for the same will be obtained from the Director CGHS, to compare the bulk supply of medicine in two Phases;

Phase-I. Condition of container, container cartons, quantity, labels, batch number on packing unit and accounting unit, date of manufacture, book reference and expiry date where ever applicable.
Phase-II. One accounting unit from each packing unit or one Accounting Unit among 100 accounting units in case heavy supply will be randomly picked up from the lot and the same will be compared with control sample for taste, color, consistency, shape, size, weight, hardness, brittleness, fineness, form and consistency of the medicine as per formulation, along with lab reports.

B. If the panel is not satisfied with the supply and rejects the medicine, the same will be informed to the firms for replacement of the medicine, except medicines rejected on quality basis which will be destroyed at stores, at the expense of the firm.

C. If the concerned firm wishes to contest the decision of the panel the same will be placed to a Medical Expert Opinion Committee of Physicians of the CGHS/ Institutions/ organizations of the Deptt of AYUSH. The decision of the Committee will be final and binding. Annexed.

14. Preparation of Inspection notes and issue of medicines:

After approval of the bulk supply medicine the inspection notes will be prepared by the receipt Section of this Depot and placed before the Store Officer In charge for further physical checking and signature. After this exercise the medicines will be handed over to the concerned Section in charge to take into charge and the medicines will then be issued to the dispensaries /Units / hospitals on indents. While preparing the inspection notes the priority to be given to IMPCL firm, without giving up the first come first serve principle.

15. Procurement through local purchase system:

Medicines will be procured from approved local chemists under the following circumstances:

A. If a formulary medicine is not available in the Store, dispensaries, units and Hospital and medicine of equal therapeutic value is not available in the existing formulary.

B. Non formulary medicine prescribed by the in- charges of the Dispensaries / Units / Hospital, Adviser (AY) / Med. Supdt. Ay.
Hospital, Lodi Road / Joint Adviser / Deputy Adviser (AY) CMO I/c AMSD to the beneficiaries to be purchased. For outside Delhi in-charge of the concerned Dispensaries / Units.

C. Medicines of IPD formulary, as and when prepared, and not available in Store.

16. **Validity of Local chemist appointment:**

The appointment of local chemists will be for a 2 year period by inviting applications through advertisements in all the local leading newspapers, webpage of the Ministry and CGHS. The tenders may also be issued on request by AMSD.

17. **Local Purchase Tender Committee:**

The tenders will be opened by the tender Opening Committee in the presence of the representatives of the applicant chemists, as per provisions of the General Financial Rules, which will scrutinize the tender documents and present the information, in tabular form. The Committee in the process of evaluation/examination of tenders may visit premises of those chemists who were found fulfilling the conditions for verification of location and stock position. The Committee may also recommend local chemists for purchase of medicines. The recommendation of the Local Purchase Tender Committee will be required to be approved by the Ministry, in accordance with the provisions of the GFRs, before final appointment of chemist and allocating them dispensaries/units and hospital.

18. **Penalty clause.**

In order to rationalize the inflow and out flow of medicines and to maintain the stocks at both receiving ends (Stores and dispensing sites) time period for supply of medicines is very vital. To stream line and discourage the firms from delaying the supplies levying penalty is one option.

A. Bulk purchase of medicines needs to be supplied within 60 days from the date of issue of supply orders.
B. As per Ministry of Finance manual @ 0.5% per week or part thereof for the delayed supply will be applied from day 61 to day 90. After 90 days time period the supply order stands cancelled.
C. In conditions where the supply of medicine is on time, but the received medicines are rejected, and replacement by the firm is
delayed beyond one month from the date of issue of letter by AMSD, break days will be counted and accordingly penalty will be imposed as per point no.2. (Days between date of supply order to date of receipt of medicines and from the date of issue of letter for replacement to date of receipt of medicine).

D. IMPCL is excluded from the purview of penalty clause as it belongs to the Ministry and medicines are supplied throughout the year continuously and regularly.

E. Any firm found guilty / indulges in malpractices / black listed for various reasons, will be barred for 5 years or for 3 tender tenures, whichever is earlier.

19. Incorporation of detailed clause for resolution of disputes, fall clause, and Tolerance clause in the rate contract tender enquiry is required.

20. Since it was decided to issue direct tender enquiry for conclusion of the Rate Contract, in the bid document, the eligibility, along with above laws and EMD of rupees 25,000/- for a period of 4.5 months and performance security of rupees 50,000/- for a period of 3 years to be incorporated.


Unapproved sample medicines pertaining to previous tender to be collected from the store depot on or before submission of the tender documents for the current tender procedures and in future also to take back the unapproved samples after expiry of financial year otherwise all the samples will be destroyed by the Ayurvedic Medical Store Depot without any communication in this regard.
Annexure -I

Constitution of Various Committees indicated in the document:

As and when expert opinion is required, one or more experts in the field may be incorporated in the respective Committee by nomination of Director, CGHS.

1. **OPD medicines Formulary Committee:**
   - MS, Ayurveda Hospital, Lodhi Rd., New Delhi. Chairman
   - Two senior Ayurveda Physicians of CGHS Members
   - In-charge Ayurvedic Medical Store Depot Member Secretary.

2. **Tender Opening Committee:**
   - MS, Ayurveda Hospital, Lodhi Rd., New Delh. Chairmen
   - Accounts Officer, CGHS. Member
   - Ol/c CGHS Ay.M. Store Depot. Member Secretary.

3. **Medicine Selection Committee:**
   - MS, Ayur. Hospitals, Lodhi Rd,N.D. Chairman.
   - Nominee of D/o AYUSH/ Medicine Expert
   - Director, PLIM Technical Expert.
   - Senior Ayurveda Physician of CGHS Member
   - In-charge Ayur. Medical Store Depot Member Secretary.

4. **Provisioning Committee:**
   - Medical Supdt. CGHS Ay. Hospital, L.R. N.D. Chairman.
   - Senior most C.M.O. of each Zone, CGHS, Delhi. Member
   - Accounts Officer, CGHS H.Q. Member
   - Officer nominee from IFD, MOHFW. Member
   - Ol/c CGHS AMSD. Member Secretary.

\[\text{Signature}\]

\[28/2/10\]

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Barrak No. 8 & 10.
Shahjahan Road, N. Delhi-110011
5. **Local Purchase Tender Committee:**
   - Medical Supdt. CGHS Ay. Hospital, L.R. N.D.
   - Senior Officer Nominee from Ministry.
   - Accounts Officer, CGHS headquarters.
   - Nominee from IFD, MOHFW.
   - I/c CGHS Ay. Store Depot.

6. **Medical Expert Opinion committee.**
   - M.S. Ayurvedic Hospital.
   - Director PLIM.
   - Senior most C.M.O.Ayurveda.
   - Officer I/c AMSD-Member Secretary.

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**Signatures:**

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